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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,669

11/08/2005

Hesson Chung

HANO-001

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BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,669	Applicant(s) CHUNG ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,10-13,16,27-33,37,38,42,43,48-51,54 and 65-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,5,6,10-13,16,27-33,37,38,42,43,48-51,54 and 65-74.

DETAILED ACTION

Reconsideration of Restriction Requirement

The Examiner thanks the Applicants for their timely reply filed on 7 February 2008, in the matter of 10/521,669.

However, upon further consideration of the claims submitted by Applicants, a new restriction requirement follows. Group I, has been reorganized into groups I and II, as presented below. Claims 28-30, like claims 31-32, represent a method of preparing the paclitaxel composition of Group I. Claims 66-69, like claims 70-71, represent a method of preparing the paclitaxel composition of Group III.

No further elections of species have been added to ease the burden to the examiner.

The submission of this Requirement for Restriction, supersedes and vacates that which was previously submitted and originally mailed on 8 November 2007. It also be noted that this newly submitted Requirement for Restriction is in response to the same amended claim set (submitted 8 November 2005) that was originally restricted by the action of 8 November 2007.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 5, 6, 10-13, 16, 27, 72, and 73, drawn to a paclitaxel composition.

Group II, claims 28-30, drawn to a method of manufacturing the composition of Group I.

Group III, claims 31 and 32, drawn to a method of manufacturing the composition of Group I.

Group IV, claims 33, 37, 38, 42, 43, 48-51, 54, 65, and 74, drawn to a paclitaxel composition with an emulsifier.

Group V, claims 66-69, drawn to a method of manufacturing the composition of Group III.

Group VI, claims 70 and 71, drawn to a method of manufacturing the composition of Group III.

The inventions listed as Groups I through VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there is no special technical feature since U.S. Patent 6,531,139, teaches a composition comprising a monoolein, an oil, and paclitaxel.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The paclitaxel-based formulation (claim 11) further limiting the additive to: (i) a type of insoluble drug, (ii) an alcohol, or (iii) a polyol, as cited in claim 12.

The paclitaxel-based formulation (claim 12) further limiting the insoluble drug to one of those cited in claim 13.

The paclitaxel-based formulation (claim 13) further limiting the insoluble drug to one of those cited in claim 16.

The method of preparing the paclitaxel-based formulation (claim 1) further limiting the means for speeding up dissolution process: (i) heating mixture of step 1, or (ii) heating and sonicating the mixture of step 2.

The paclitaxel-based formulation (claim 49) further limiting the additive to: (i) a type of insoluble drug, (ii) an alcohol, or (iii) a polyol, as cited in claim 50.

The paclitaxel-based formulation (claim 50) further limiting the insoluble drug to one of those cited in claim 51.

The paclitaxel-based formulation (claim 51) further limiting the insoluble drug to one of those cited in claim 54.

The method of preparing the paclitaxel-based formulation (claim 66) further limiting the means for speeding up dissolution process: (i) heating mixture of step 1, (ii) heating the mixture of step 2 or (iii) heating and sonicating the mixture of step 2.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The paclitaxel-based formulation (claim 11) further limiting the additive to: (i) a type of insoluble drug, (ii) an alcohol, or (iii) a polyol, as cited in claim 12.

The paclitaxel-based formulation (claim 12) further limiting the insoluble drug to one of those cited in claim 13.

The paclitaxel-based formulation (claim 13) further limiting the insoluble drug to one of those cited in claim 16.

The method of preparing the paclitaxel-based formulation (claim 1) further limiting the means for speeding up dissolution process: (i) heating mixture of step 1, or (ii) heating and sonicating the mixture of step 2.

The paclitaxel-based formulation (claim 49) further limiting the additive to: (i) a type of insoluble drug, (ii) an alcohol, or (iii) a polyol, as cited in claim 50.

The paclitaxel-based formulation (claim 50) further limiting the insoluble drug to one of those cited in claim 51.

The paclitaxel-based formulation (claim 51) further limiting the insoluble drug to one of those cited in claim 54.

The method of preparing the paclitaxel-based formulation (claim 66) further limiting the means for speeding up dissolution process: (i) heating mixture of step 1, (ii) heating the mixture of step 2 or (iii) heating and sonicating the mixture of step 2.

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The following claims are generic: 11-13, 28, 49-51, and 66.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: there is no special technical feature since U.S. Patent 6,531,139, teaches a composition comprising a monoolein, an oil, and paclitaxel.

No telephone call was made to request an oral election to the above restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit
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